

INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

Preventing Medication Errors

Institute of Medicine Committee on Identifying and Preventing Medication Errors

July 2006

Task and Scope

At the urging of the Senate Finance Committee, Congress directed CMS to sponsor IOM to carry out a study:

- Task:
 - To develop a national agenda for medication error reduction based on estimates of the incidence of medication errors and efficacy of error prevention strategies.
- Scope:
 - All components of the medication use process
 - Prescription, OTC, complementary/alternate medications
 - Hospital, long-term and community care

Conclusions

- Medication errors are very common in every setting in which medications are used and present a risk to millions of Americans every day
- There are many opportunities to make medication use safer
- Safe medication use will require actions at all levels of the health care system, including providers, patients, health care institutions, educator, regulators, payors and legislators
- More information is needed so we can learn in the real world how to prevent medication errors

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Key Definitions

- **Error:** The failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). An error may be an act of commission or an act of omission.
- **Medication error:** Any error occurring in the medication use process.
- **Adverse drug event (ADE):** Any injury due to medication.

Frequency of Medication Errors and Preventable Adverse Drug Events Is Very Serious Cause for Concern

- On average a hospital patient is subject to at least one medication error per day (ref)
- Substantial variations in error rates are found across facilities
- At least 1.5 million preventable ADEs occur each year:
 - Hospital care: Classen et al., (1997) projected 380,000; Bates et al. (1995) 450,000
 - Long-term care: Gurwitz et al. (2005) projected 800,000
 - Among outpatient Medicare patients: Gurwitz et al. (2003) projected 530,000
- Major exclusion: errors of omission

Morbidity Due to Medication Errors Is Costly

- Our understanding of these costs is very incomplete
 - Hospital care: \$3.5 billion (2006 dollars) (Bates et al., 1997)
 - Long-term care: no cost estimate available
 - Among outpatient Medicare patients: \$887 million (2000 dollars) (Field et al., 2005)
- Major cost exclusions:
 - Drug use without a medically valid indication
 - Failure to receive drugs that should have been prescribed
 - Failure of patients to comply with prescribed medication regimens
 - Lost earnings, compensation for not being able to carry out household duties, and compensation for pain and suffering
 - Errors that do not result in harm but create extra work

Overview of Recommendations

- Improved provider-patient partnership is vital
 - Actions for consumers and providers (rec. 1); improved consumer-oriented drug information (rec. 2)
- Electronic prescribing (by 2010) and monitoring for errors is essential (rec. 3)
- Enormous knowledge deficits must be addressed
 - Improved naming, labeling and packaging, and review of free sample use (rec. 4); standards for health IT (rec. 5); research agenda on safe medication use (rec. 6)
- Oversight, regulatory organizations, and payers should motivate error reduction and enhance professional competency (rec. 7)

Improved Provider-Patient Partnership Is Vital (1)

- By becoming more informed and engaged, consumers (and their surrogates) may decrease the probability of experiencing a medication error
- Consumers (and surrogates) should be empowered as partners with providers in their care, with appropriate communication, information, and resources to support them.
- Government and other participants should improve consumer-oriented written and electronic information resources.

Improved Provider-Patient Partnership Is Vital (2)

- **Recommendation 1:** To improve the quality and safety of the medication-use process, specific measures should be instituted to strengthen patients' capacities for sound medication self-management. Specifically:
 - Patients' rights regarding safety and quality in health care and medication use should be formalized at the state and/or federal levels and ensured at every point of care.
 - Patients (or their surrogates) should maintain an active list of all prescription drugs, over-the-counter (OTC) drugs, and dietary supplements they are taking; the reasons for taking them; and any known drug allergies. Every provider involved in the medication-use process for a patient should have access to this list.

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Improved Provider-Patient Partnership Is Vital (2) *Continued*

- Providers should take definitive action to educate patients (or their surrogates) about the safe and effective use of medications. They should provide information about side effects, contraindications, and how to handle adverse reactions, as well as where to obtain additional objective, high-quality information.
- Consultation on their medications should be available to patients at key points along the medication use process (during clinical decision making in ambulatory and inpatient care, at hospital discharge, and at the pharmacy).

Improved Provider-Patient Partnership Is Vital (3)

- Consumers should be able to obtain quality information about medications not only from their provider, but also from the pharmacy, Internet resources, and community-based resources. However:
 - Current materials are inadequately designed for consumers to read, comprehend, and act on.
 - Reliable Internet information is difficult to find.
 - In addition, there is a need for additional resources beyond pharmacy leaflets and Internet information that can be provided on a national scale.

Improved Provider-Patient Partnership Is Vital (4)

- **Recommendation 2:** Government agencies (i.e., AHRQ, CMS, FDA, NLM) should enhance the resource base for consumer-oriented drug information and medication self-management support. Such efforts require standardization of pharmacy medication information leaflets, improvement of online medication resources, establishment of a national drug information telephone helpline, the development of personal health records, and the development of a national medication safety dissemination plan.
 - Pharmacy medication information leaflets should be standardized to a format designed for readability, comprehensibility, and usefulness to consumers. The leaflets should be made available to consumers in a manner that accommodates their individual needs, such as those associated with variations in literacy, language, age, and visual acuity.

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Improved Provider-Patient Partnership Is Vital (4) *Continued*

- NLM should be designated as the chief agency responsible for Internet health information resources for consumers. Drug information should be provided through a consumers' version of the DailyMed program, with links to NLM's Medline Plus program for general health and additional drug information.
- FDA, CMS, and NLM working together, should undertake a full evaluation of various methods for building and funding a national network of drug information helplines.
- CMS, FDA, and NLM should collaborate to confirm a minimum data set for personal health records and develop requirements for vendor self-certification of compliance. Vendors should take the initiative to improve the use and functionality of personal health records by incorporating basic tools to support consumers' medication self management.
- A national plan should be developed for widespread distribution and promotion of medication safety information. Health care provider, community-based, consumer, and government organizations should serve as the foundation for such efforts.

Electronic Prescribing and Monitoring for Errors Is Essential (1)

- Almost impossible for prescribers to have current knowledge about every medication they prescribe;
- Paper-based prescribing is associated with high medication error rates;
- Patient handoffs between care sites and providers often lead to medication errors;
- Medication error reduction is an ongoing activity.

Electronic Prescribing and Monitoring for Errors Is Essential (2)

- **Recommendation 3:** All health care organizations should immediately make complete patient-information and decision-support tools available to clinicians and patients. Health care systems should capture information on medication safety and use this information to improve the safety of their care delivery systems. Health care organizations should implement the appropriate systems to enable providers to:
 - Have access to comprehensive reference information concerning medications and related health data.
 - Communicate patient-specific medication-related information in an interoperable format.

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Electronic Prescribing and Monitoring for Errors Is Essential (2) *Continued*

- Assess the safety of medication use through active monitoring and use these monitoring data to inform the implementation of prevention strategies.
- Write prescriptions electronically by 2010 and all pharmacies be able to receive them electronically, also by 2010. All prescribers should have plans in place by 2008 to implement electronic prescribing.
- Subject prescriptions to evidence-based, current clinical decision support.
- Have the appropriate competencies for each step of the medication use process.
- Make effective use of well-designed technologies, which will vary by setting.

Enormous Knowledge Deficits Must Be Addressed (1)

- Better risk/benefit information is needed for prescription drugs, particularly, for specific populations – children, elderly, patients with renal dysfunction, patients with multiple comorbidities.
- Drug naming, labeling and packaging problems lead to medication errors.
- Growing concerns about the way free samples are distributed – lack of documentation of medication use, bypassing of the standard prescribing and dispensing services incorporating drug-interaction checking and pharmacy counseling services.

Enormous Knowledge Deficits Must Be Addressed (2)

- **Recommendation 4:** Enhancing the safety and quality of the medication-use process and reducing errors requires improved methods for labeling drug products and communicating medication information to providers and consumers. For such improvements to occur, materials should be designed according to designated standards to meet the needs of the end user. Industry, AHRQ, the FDA, and others as appropriate (e.g., U.S. Pharmacopeia, Institute for Safe Medication Practices) should work together to undertake the following actions to address labeling, packaging, and the distribution of free samples:
 - The FDA should develop two guidance documents for industry: one for drug naming and another for labeling and packaging. The FDA and industry should collaborate to develop (1) a common drug nomenclature that standardizes abbreviations, acronyms, and terms to the extent possible, and (2) methods of applying failure modes and effects analysis to labeling and packaging.

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Enormous Knowledge Deficits Must Be Addressed (2) *Continued*

- Additional study of optimum designs for all drug labeling and information sheets to reflect human and cognitive factors should be undertaken. Methods for testing and measuring the effect of the materials on providers and consumers should also be established including methods to field test materials. The FDA, NLM, and industry should work with consumer and patient safety organizations to improve the nomenclature used in consumer materials.
- The FDA, the pharmaceutical industry, and other stakeholders should collaborate to develop a strategy for expansion of unit-of-use packaging for consumers to new therapeutic areas. Studies should be undertaken to evaluate different methods of presenting unit-of-use packaging and designs that best support different consumer groups in their medication self management
- The Agency for Health Care Research and Quality should fund studies that evaluate the impact of free samples on overall patient safety, provider prescribing practices, and consumer behavior (for example, adherence), as well as alternative methods of distribution that can improve safety, quality, and effectiveness.

Enormous Knowledge Deficits Must Be Addressed (3)

- Realizing the benefits of health IT is hampered by lack of common data standards for system integration and well-designed interfaces for end users:
 - There is no complete, standardized set of terms, concepts, and codes to represent drug information.
 - There is no standardized method for presenting safety alerts according to severity and/or clinical importance - alert fatigue is a big problem.
 - Many systems lack intelligent mechanisms for relating patient-specific data to allowable overrides, such as those associated with a particular patient and drug allergy alert or duplicate therapy request.

Enormous Knowledge Deficits Must Be Addressed (4)

- **Recommendation 5:** Industry and government should collaborate to establish standards affecting drug-related health information technologies, specifically:
 - The NLM should take the lead in developing a common drug nomenclature for use in all clinical information technology systems based on the standards for the national health information infrastructure.
 - AHRQ should take the lead in organizing safety alert mechanisms by severity, frequency, and clinical importance to improve clinical value and acceptance.

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Enormous Knowledge Deficits Must Be Addressed (4) *Continued*

- AHRQ should take the lead in developing intelligent prompting mechanisms specific to a patient’s unique characteristics and needs; provider prescribing, ordering, and error patterns; and evidence-based best-practice guidelines.
- AHRQ should take the lead in developing user interface designs based on the principles of cognitive and human factors and the context of the clinical environment.
- AHRQ should support additional research to determine specifications for alert mechanisms and intelligent prompting, and optimum designs for user interfaces.

Enormous Knowledge Deficits Must Be Addressed (5)

- Large gaps exist in our understanding of medication error incidence rates, costs, and prevention strategies:
 - Primary focus of research in the next decade should be prevention strategies and their implementation.
 - Priority areas for research on incidence rates are care transitions, specialty ambulatory clinics, psychiatric care, the administering of medications in schools.
 - A better understanding of the costs/consequences of errors in all care settings needed to inform decisions about investing in error prevention strategies.

Enormous Knowledge Deficits Must Be Addressed (6)

- **Recommendation 6:** Congress should allocate the necessary funds and AHRQ should take the lead, working with other government agencies such as CMS, FDA and NLM, in coordinating for a broad research agenda on the safe and appropriate use of medications across all care settings, covering research methodologies, incidence rates by type and severity, costs of medication errors, reporting systems, and in particular, further testing of error prevention strategies.

Oversight, Regulation and Payment

- **Recommendation 7:** Oversight and regulatory organizations and payers should use legislation, regulation, accreditation, and payment mechanisms and the media to motivate the adoption of practices and technologies that can reduce medication errors, and to ensure that professionals have the competencies required to deliver medications safely.
 - Payers and purchasers should continue to motivate improvement in the medication-use process through explicit financial incentives.
 - CMS should evaluate a variety of strategies for delivering medication therapy management.

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Oversight, Regulation and Payment

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- Regulators, accreditors, and legislators should set minimum functionality standards for error prevention technologies.
- States should enact legislation consistent with and complementary to the Medicare Modernization Act's e-prescribing provisions and remove existing barriers to e-prescribing.
- All state boards of pharmacy should undertake quality improvement initiatives related to community pharmacy practice.
- Medication error reporting should be promoted more aggressively by all stakeholders (with a single national taxonomy used for data storage and analysis).
- Accreditation bodies responsible for the oversight of professional education should require more training in improving medication management practices and clinical pharmacology.